**PARTICIPANT ID:** …………………………

**INFORMED CONSENT FOR THE STORAGE OF BIOLOGICAL SPECIMENS**

## **Study Title:**

Give a clear and concise title of the research.

## **Introduction**

You/your child is being invited to take part in a research study. Before you decide whether you/ your child can participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

## **What is the purpose of the study?**

Provide a brief description of the purpose or **what the study aims to achieve**.

## **Why store a specimen*?***

*[List the samples collected if more than one e.g., blood, saliva and then write the rational for storing the samples].*

## **What quantity of my/ my child’s sample will be stored?**

If you agree to storage of your/your child’s *[insert sample type e.g. blood]* sample, *[insert quantity to be stored]*.

## **Handling of stored samples**

Your/ your child’s *[insert sample type]* samples will be stored at the *[insert study site or other site]* in *[location]* and also at the …………………. laboratory or other laboratories located outside Uganda *<<if applicable>>*

## **How long will my/my child’s sample be kept?**

Your/ your child’s sample may be stored for a long time but not longer than 5 years.

## **Will my/ my child’s taking part in this study be kept confidential?**

Confidentiality will be maintained at all times. All samples will be coded (but it will be possible to link results to anonymized data collected from this study). Once the study has been completed, we will ensure that no one can link your/ your child’s identity to your/his/her clinical details.

## **What policies will govern the use of my/my child’s sample in future research?**

By giving broad consent, you agree that your/your child’s sample may be used in future research related to the scope described in the initial consent form. Further approval will be sought from an accredited ethics committee for any future studies other than the one you are currently enrolled in. *[Study site]* will be responsible for securely storing and managing all samples obtained as part of this project for research purposes.

With ethics committee approval, a small portion of your/ your child’s sample will be provided to other researchers and may be sent to countries outside Uganda. *<<Only if you plan to export samples to foreign countries>>*

## **Withdrawal of Consent and Destruction of Samples**

You may withdraw your consent/ your parental consent to store your/ your child’s sample without affecting your/his/her participation in the main study*.*

To withdraw your consent/ parental consent for storage of your/ your child’s samples, you will contact the study doctor or the research office at *[study site]*, because only he/she has access to all of your/his/her identifying information. If you withdraw your/ your parental consent for the storage during this time, you may request that your/ your child’s *[include other categories of biological samples]* sample to be destroyed and no longer used in research. Any research results obtained prior to your parental withdrawal of consent will however be used.

## **What are risks that may be associated with storage of your child’s sample?**

The main potential risk is loss of confidentiality. However, several measures have been put in place to ensure that your/ your child’s information is not leaked to individuals who are not part of this research *[list measures specific to your study site, such as coding, password protection, or restricted access]*.

## **What are the possible benefits of taking part?**

It is unlikely that the study will be of direct benefit to you/ your child; however, it may benefit your child and other patients who will be on *[Insert disease(s) under investigation]* treatment in the future.

## **Who is organizing and funding the research?**

This study is being conducted by [insert name of institution] and is funded by *[insert name of the funding organization]*.

## **Who has reviewed the study?**

This study has been reviewed by the School of Biomedical Sciences Research Ethics Committee (SBSREC).You may contact the chairperson of SBSREC if you have any questions regarding your/ your child’s right as a study participant at any time, Dr. Moses Ocan at email: biomedicalresearch62@gmail.com or 0782 355 302.

## **Thank you for reading the information about our research project. If you agree for yourself/ your child to participate, please read and sign this form.**

**Consent for storage and use in possible future research projects.**

……………………………………………………. has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study.

I understand that the *[insert type of specimen, e.g., blood, urine]* sample(s) collected from me/my child may be stored securely by *[insert study site]* and *[insert other institution, if applicable]*, as described in the information sheet.

I understand that the sample(s) and related data will be identified using a unique code and that my/my child’s identity will not be disclosed.

I give permission for the stored sample(s) and data to be used in future research related to the scope described in this consent, provided such research is reviewed and approved by a Research Ethics Committee.

Do you agree to the storage and future use of your/my child’s sample(s) and related data as described above? *<<Please tick one box below to indicate your choice>>*

 I Agree

 I don’t Agree

**SIGNATURE**

Name of Participant/ Participant’s Parent/ Guardian: ……………………………………………...

Signature of the Participant/ Participant’s Parent/ Guardian: ……………………………………...

Make a thumbprint in the box below << *if the participant can’t sign*>>

 Date: *[DD/MM/YYYY]*

Name of Person Administering Consent: ……………………………………………...

Position/ Title of Person Administering Consent: ……………………………………..

Signature of Person Administering Consent: …………………………………….........

Date: *[DD/MM/YYYY]*

*\*If the participant or participant’s parent/ guardian is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant or participant’s parent/ guardian, and after they have orally consented to their participation in the study, and have either signed the consent form or provided their fingerprint, the witness should sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by the participant or participant’s parent/ guardian and that informed consent was freely given by the participant or participant’s parent/ guardian.*

Name of Person Witnessing Consent: ………………………………………………....

Signature of Person Witnessing Consent: …………………………………………......

Date: *[DD/MM/YYYY]*